

REMARKS/ARGUMENTS

The Office Action mailed 05/13/2003 has been carefully reviewed. The Office Action mailed 05/13/2003 is "non-final." Reconsideration of this application, as amended and in view of the following remarks, is respectfully requested.

The claims presented for examination are: claims 1-9 and 36-43.

Claims 10-35 were subject to a restriction requirement in the Office Action mailed 05/15/2002 and are directed to a non-elected invention(s).

Claim Objection

Claim 41 was "objected to." Applicants have amended claim 41 to change the term "capture legend" to the term "capture ligand" and believe this overcomes the Examiner's objection.

35 USC §112 Rejections

In Office Action mailed 05/13/2003, claims 1-9 and 36-40 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-9 and 36-40 have been amended. Applicants submit that the specification contains details sufficient for one skilled the art to make and use the invention defined by amended Claims 1-9 and 36-40. In particular, Applicants direct the Examiner's attention to original paragraph [0038] of the specification on page 11 that shows basis for amended Claims 1-9 and 36-40.

In Office Action mailed 05/13/2003, claims 41-43 were rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 41-43 have been amended. Applicants submit that the specification contains details sufficient for one skilled the art to make and use the invention defined by amended claims 41-43 and complies with the written description requirement. In particular, Applicants direct the Examiner's attention to original paragraph [0038] of the specification on page 11 that shows basis for amended Claims 41-43.

In Office Action mailed 05/13/2003, claims 1-9 and 36-43 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Claims 1-9 and 36-43 have been amended and Applicants respectfully submit that amended claims 1-9 and 36-43 particularly point out and distinctly claim the subject matter which applicant regards as the invention and are not indefinite. Claims 1-9 and 36-43 include the steps "providing a multiplicity of optically encoded microbeads," "providing said microbeads with a capture ligand," "providing said microbeads with bioagent-specific antibodies," "containing said optically encoded microbeads," and "adding a sample to said contained microbeads." These steps particularly point out and distinctly claim the subject matter which applicant regards as the invention and claims 1-9 and 36-43 are not indefinite.

35 USC §102 Rejection

In Office Action mailed 05/13/2003, claims 1-3, 5-6, 36, and 40 were rejected under 35 USC §102 (b) as allegedly being anticipated by Pyle et al (US Patent No. 5, 821,066). The rejected claims have been amended and the claims as amended now include a combination of a number of steps basically as set out below:

1. "providing a multiplicity (quantity) of optically encoded microbeads"
2. "providing said microbeads with (adding) a capture ligand"
3. "providing said microbeads with (adding) bioagent-specific antibodies"

4. "containing said optically encoded microbeads"
5. "adding a sample to said contained microbeads"
6. "placing said contained microbeads and said sample in a mixing holder for sufficient time for a targeted biological sample to adequately bind said microbeads"
7. "adding fluorescent labeled antibodies to said contained microbeads and said sample for attachment to said bioagent-specific antibodies,"
8. "attaching at least some of said microbeads to (providing) a disposable capture substrate containing an array of attachment sites for attaching said microbeads thereto"
9. "washing said substrate and attached microbeads"
10. "inserting said substrate into an optical detection system"
11. "optically decoding said microbeads for identification and measurement of said target biological sample"

The Pyle et al reference describes a rapid method for the detection, identification and enumeration of specific respiring microorganisms. The method includes steps of a) passing a microbial sample through a collecting device to capture the cells; b) adding to the collecting device a fluorochrome dye specific for the detection of respiring cells and allowing the dye to incubate; c) treating the collecting device with a reactive fluorescent antibody which reacts with a target microorganism of interest present in said microbial sample; d) mounting the collecting device for examination by fluorescence microscopy in which a suitable light system is used to excite the fluorochrome dye and fluorescent antibody to fluoresce; and e) quantifying the respiring cells. Alternative embodiments include the use of immunomagnetic beads and other means of cell capture, and employing fluorescent oligonucleotide probes rather than fluorescent antibodies. (See Abstract)

Applicant respectfully submits that the Pyle et al reference does not show the steps of the claims now presented for examination. As stated in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2nd 628, 631 USPQ 1051, 1053 (Fed. Cir.

1987), "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." Since the steps of the claims now presented for examination are not shown by the Pyle et al reference, the rejection is unsupported by the art and should be withdrawn.

35 USC §103 Rejection

In Office Action mailed 05/13/2003, claims 41-43 were rejected under 35 USC §103 as allegedly being unpatentable over Pyle et al (US Patent No. 5, 821,066) and Nazareth et al (US Patent No. 6,319,676). The rejected claims have been amended and the claims as amended now include a combination of a number of steps as set out above.

Applicants respectfully traverse the rejection of claims 41-43 under 35 U.S.C. §103. The cited references do not teach the claimed combination. There is no suggestion in the references to form a proper combination. The cited references do not provide a teaching of the claimed combination. The Pyle et al reference does not show the steps of the claims now presented for examination and the Nazareth et al reference does provide the missing steps and does not provide a teaching of the claimed combination.

SUMMARY

The undersigned respectfully submits that, in view of the foregoing amendments and the foregoing remarks, the rejections of the claims raised in the Office Action dated 05/13/2003 have been fully addressed and overcome, and the present application is believed to be in condition for allowance. It is respectfully requested that this application be reconsidered, that the claims be allowed, and that this case be passed to issue. If it is believed that a telephone conversation would expedite the prosecution of the present application, or clarify matters with regard to its allowance, the Examiner is invited to call the undersigned attorney at (925) 424-6897.

Respectfully submitted,



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